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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,224	06/05/2006	Frode Brakstad	VITL.0101PUSA	3744

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ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,224	BRAKSTAD ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed June 17, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1, 5-7 have been amended.

   b. Claim 15 has been added.

2. Claims 1, 3-8, 12-15 are pending in the case.

3. Claims 1, 3-8, 12-15 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

7. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3-8, 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed,

had possession of the claimed invention. The newly amended claim 1 recites that the B6, B9, and B12 vitamins in the portions of the claim are to compensate for the loss of the B6, B9, and B12 vitamins due to carboxylic acid metabolism. The specification does not provide support for the recitation. Applicant has directed that paragraphs 4, 7, and 11 of the publish application provides support for the amendment but upon review of the specific paragraphs there is no support for the specific recitation that B6, B9, and B12 in a combined amount of 10-50mg/gram dry weight of the supplement were included in the composition in these amounts expressly for the compensation of these vitamins because of carboxylic acid metabolism. Further review of the specification did not yield support for the new amendment. It is noted that the recitation of intended motivation does not have patentable weight in the claim. The new matter also applies to the dependent claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (U.S.Pat. Pub. No. 2002/0150653) in view of The Food and Nutrition Board (Dietary Reference Intakes (DRIs); Estimated Average Requirements for Groups).

Bailey et al. teaches the concept of a food, feed, and vitamin preparations comprising folates and multivitamins for human of animal consumption. The

compositions were preferably stored with antioxidants and reducing agents to extend shelf life. The pH of the final composition can be optimized based on the desired stability properties, preferably with acidity less than about pH 4. The compositions exemplified comprised citric acid, ascorbic acid, vitamin E, pyridoxine (vitamin B6), folic acid (vitamin B9), vitamin B12 (cyanocobalamin), ferrous fumarate, and silica (desiccant).

Several examples are taught Bailey et al. with different forms including cereal, tablets, drinks, cat food, bird feed, and infant formula with varying amounts of vitamins and minerals within the RDI and far beyond the RDI (see Example 6). Bailey teaches that vitamin and nutrient components can be present in amounts that vary considerably from NRC recommendations and can be greater than 25%, greater than 50% and even greater than or equal to 100% of the daily requirement for the nutrient. Several examples have ascorbic acid or citric acid and have the ratios for the acid with B6, B9, and B12 (i.e. Example 3/tablet-B9:ascrobic=0.545mg/0.06g=9.08mg/g, B12:ascorbic=6ug/0.06g=100ug/g).Bailey also teaches the method of administering the compositions to humans and animals, including horses, for the treatment of conditions including intestinal malabsorption, increasing the dietary intake of folate which improves performance as it would improve immune response and reduce risks to cancer, peripheral vascular disease, and nervous system disorders as Bailey teaches that a deficiency in folate would result in a susceptibility to these conditions (see full document, specifically Abstract, Paragraph 3-7, 11, 15-21, 30-36, 38-49).

Bailey et al. does not expressly teach an example with the specifics of where to total amount of the B6, B9, and B12 together is 10-50mg/g of the supplement, at the specific range of 0.5-30mg/g of the acid, 0.1-10mg/g of the acid, and 1-1500ug/g of the acid, wherein the acid is formic, citric, lactic, propionic, ascorbic, fumaric, acetic, or benzoic. Bailey also does not teach the administration of the supplement based on weight in humans.

Bailey does teach the combination of all these elements, e.g. carboxylic acids (such as ascorbic acid and citric acid) and vitamin B6, B9, and B12, together as supplements in food, feed, and vitamin preparations. Bailey also provides examples of these forms citing that the amounts of these components can be varied based on the nutritional requirements.

The Food and Nutrition Board (Dietary Reference Intakes (DRIs); Estimated Average Requirements for Groups) teaches that there are general estimated average requirements for vitamin intake for different groups, ages, and gender. There is also different recommended requirement for infants, children, and adults.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to optimize the amounts of the vitamins in the supplement based on and beyond the amounts in the DRI table, and modify the supplement as needed for the form and patient population, as suggested by Bailey and the Food and Nutrition Board, and produce the instant invention. It would have been obvious to one of skill in the art to modify the form of the supplement dependent the target population,

mode of administration, and vitamin levels of the components as Bailey teaches several forms with a range of vitamin levels and combinations and teaches that these levels vary considerably depending on the desired amounts/levels. The amounts desired can be present in the recommended levels (e.g. RDI or NRC) but can also vary considerably from these recommendations depending on the manufacturers' desired target population, delivery form, and therapeutic profile.

Bailey expressly states that manufacture often exceed the dosage recommended by the NRC (e.g. folate), and the amounts for the daily requirement can be greater than 10% and even greater than 100%. As shown by the examples, the components such as vitamin levels and delivery forms can be modified depending the mode of delivery and the vitamin content desired. The Food and Nutrient Board teaches general recommended intakes and also teaches that they vary depending on the targeted population. The amounts vary when it is an infant, child, or an adult which also goes to body weight as you cannot give the same of amount of a vitamin that is safe for an adult to an infant as the level may be toxic to an infant due their body size/weight. Active agents are routinely calibrated based on body weight for children and is the standard in medicine. Several examples have ascorbic acid at different levels and the excipient citric acid in tablets. It would be obvious to one of skill in the art to modify the amount of the ascorbic acid, the citric, and/or the B vitamins to attain the desired therapeutic profile and level of supplementation desired wherein the adjustment of the B vitamins, ascorbic acid, and/or the citric acid to the desired levels would also arrive the general optimal range and percent ranges. In the absence of evidence or a showing of the

criticality of the specific ratios in the claims, a general optimal range whereby the ratios and percent ranges are clustered in a nexus that can be arrived through optimization when the general conditions are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

One of ordinary skill in the art would have been motivated to do this because it is desirable to optimize the amounts of the vitamins and nutritional components in a supplement form desired for the target population to be treated as different types of animals, the age, and the sex of the animal have different requirements, as addressed in both Bailey and The Food and Nutrition Board, to attain the desired biological results for the patient population targeted.

Response to Arguments

10. Claims 1, 3-5, 8, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (U.S.Pat. Pub. No. 2002/0150653) in view of The Food and Nutrition Board (Dietary Reference Intakes (DRIs); Estimated Average Requirements for Groups).

Applicant's arguments filed 6/17/2009 have been fully considered but they are not persuasive. Applicant asserts that neither Bailey nor The Food and Nutrition Board teach Applicant's recognition of the problems associated with the loss of certain B vitamins during carboxylic acid metabolism. This is not persuasive as the recitation of intended motivation does not have patentable weight in the claims particularly in regards to a composition. In regards to the argument that the optimization of the composition components to achieve a recognized result of compensating for the loss of

certain B vitamins during carboxylic acid metabolism is not recognized in the art. This is not persuasive as addressed above, the recitation of intended motivation does not have patentable weight in the claims particularly in regards to a composition. Additionally, Bailey teaches the components of the claims and expressly teaches that the vitamin and nutrient components can be modified within the RDI and far beyond the RDI and can have amounts that vary considerably from NRC recommendations depending on the which animal the formulation is to be administered to (e.g. cat, bird, horse, human) as addressed by the different forms in Bailey (e.g. cereal, tablets, drinks, cat food, bird feed, and infant formula) and even the target age as addressed by the Food and Nutrition Board (child verses male verses female verses age group). As for Applicant's reference tot the IPEA review of Bailey, the report is fully considered but as prosecution by the IPEA, the EPO, JPO, and the U.S. are vastly different the argument is not persuasive and not commensurate in section the rejection.

Accordingly, the rejection is maintained.

11. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (U.S.Pat. Pub. No. 2002/0150653) in view of the Food and Nutrition Board (Dietary Reference Intakes (DRIs);Estimated Average Requirements for Groups) as applied to claims 1, 3-5, 8, 12-14 above, and in view of Lawrence (Nutrient Requirements and Balancing Rations for Horses).

Applicant's arguments filed 6/17/2009 have been fully considered but they are not persuasive. Applicant arguments for Bailey and The Food and Nutrition Board are addressed above. Applicant's assertion that Lawrence teaches away from the addition

of B complex vitamins is not persuasive. First, the section Applicant refers to is to maintenance diets for mature horses with high quality fresh forages which are not reflective of nutritional requirements for all horses, such as foals; and not all conditions such as training and competition conditions which are reflective of the method claims. As a result, Applicant's argument is not commensurate in scope with the claims. Additionally, Lawrence states that there is individual variation among horses which can be large and horses have never been selected for feed efficiency or uniformity. Second, a B complex vitamin means a complex with all eight B vitamins wherein supplementation with B vitamins that do not include all eight is not precluded. This is evidenced by the teaching in Lawrence that there are some deficiencies in Virginia forages that require additional supplementation such as thiamine and riboflavin (both are B Vitamins) as addressed in Table 6, and that there are oats to supplement feeds known in the art (as evidenced by McCormick-WO 2003/061401 which teaches oat feeds with vitamins including A, B6, B9, B12, and E, see Abstract). As a result, Lawrence teaches that additional supplementation with B vitamins is known and as addressed by Lawrence the nutritional requirements are variable depending on the horse and conditions wherein modifications would be made by one of skill in the art.

Accordingly, the rejection is maintained.

Conclusion

12. Claims 1, 3-8, 12-15 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612